

EXHIBIT 11

1

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL PRESCRIPTION) No. 17-md-2804
5 OPIATE LITIGATION)
6)
7 APPLIES TO ALL CASES) Hon. Dan A. Polster
8)
9

10 VIDEO DEPOSITION OF SANDRA KINSEY

11 June 7, 2019
12 9:05 a.m.

13 *HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
14 CONFIDENTIAL REVIEW*

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18 Reporter: John Arndt, CSR, CCR, RDR, CRR
19 CSR No. 084-004605
20 CCR No. 1186
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1 actually found was that HBC had a reduction in the HCP
2 shipments.

3 Q. Would you expect there to be an increase
4 in all Giant Eagle Pharmacies based on increases in DEA
5 quotas?

6 A. It's really looking at an average overall,
7 that if the DEA nationwide is -- if the DEA nationwide
8 is raising their quotas as a result of an increase in
9 prescriptions and an increase in demand for the
10 product, that a reasonable expectation is that in
11 general every pharmacy could also have that same type
12 of increase.

13 So it's very much a generalization when
14 you talk about what could be expected. In general you
15 would expect if the DEA says there's a higher demand
16 for product and there's more prescriptions, then in
17 general the pharmacies are going to rise at that same
18 rate, which is why the DEA increased their quota to
19 begin with, but what we actually found with Giant Eagle
20 is that the amount of HCP shipments declined.

21 Q. The DEA quotas are done on a nationwide
22 basis; right?

23 A. That is correct.

24 Q. So you've compared the nationwide

1 thresholds for suspicious order monitoring?

2 A. I believe the date was -- I can't
3 remember. I'd have to look it up. And what I'm
4 referring to, just to be clear, is their electronic
5 system of thresholds; right? That's what you asked me
6 for? I'm sorry.

7 Q. I did, yeah.

8 A. Yeah.

9 Q. Was there a manual threshold system at
10 some time before that?

11 A. I don't -- no, there wasn't a manual.
12 They've had -- they have had different reports that
13 have been running for years, and those reports have
14 evolved in order to flag and define different
15 thresholds. There isn't a single threshold system that
16 can be deployed that effectively -- that can
17 effectively identify a true suspicious order. So using
18 a threshold-type system is -- it's one of the tools
19 that Giant Eagle employs, and they've been using a
20 threshold system for several years, and it has evolved
21 as their technology has evolved.

22 Q. So if you go to Page 49 of your report.
23 In Paragraph 141 you reference a monthly threshold
24 system starting in 2013.

1 A. There you go.

2 Q. Is that what you're referring to?

3 A. Yeah. Told you I had to look it up.

4 Q. So that's what you're referring to when
5 you talk about the automated thresholds; right?

6 A. These are the automated reporting.

7 Q. Right. So beginning in 2013, when an
8 order was flagged using this system, would that order
9 be blocked?

10 A. This one in 2013, the order itself, it was
11 only flagged for needing further investigation. It
12 doesn't mean that the order was actually suspicious; it
13 just is a trigger that is flipped so that somebody can
14 do further investigation.

15 Q. Right. So while that investigation was
16 ongoing using the system -- starting with the one in
17 2013 that -- this monthly system that you're talking
18 about here -- first of all, what sort of employee would
19 be tasked to do that investigation?

20 A. Well, the employee -- the employee that
21 was tasked sort of -- the information would be brought
22 to the attention of the pharmacy district leader, which
23 by the way I believe in most cases is also a
24 pharmacist, and they're the ones that are the

1 operational supervisor for the store level.

2 Q. Do you know if the pharmacy district
3 leader covering Summit and Cuyahoga Counties was a
4 pharmacist?

5 A. Yes.

6 Q. And who was that?

7 A. I've read so many reports. I cannot
8 recall his name.

9 Q. So while that investigation was ongoing by
10 the pharmacy district leader, what would happen to the
11 order using -- under the 2013 system?

12 A. Well, in 2013, again, it was a flag, but
13 in 2013, that order would continue to go through.
14 However, because Giant Eagle is a captive
15 self-distributor, at any time if they had a concern
16 about an order they could certainly stop it and/or
17 quarantine the product.

18 Q. Did you assess whether that was actually
19 done in any situation, where an order was flagged under
20 the system from 2013, it went on through, and it was
21 pulled back later, quarantined or stopped?

22 A. I believe there was an order or two. I
23 may have my time frames -- but I believe there were a
24 couple of orders. However, it was not -- it may even

180

1 have been outside these two counties, but there are --
2 these are some of the questions that I asked as I was
3 looking at their controls.

4 Q. So are you aware of any orders under this
5 monthly ordering threshold system in 2013 from Summit
6 and Cuyahoga Counties that you can cite to or you
7 intend to cite to that were held or stopped after they
8 were flagged?

9 A. I don't intend to call anything out as a
10 specific example in the 2013 time frame.

11 Q. In the -- you reference in Paragraph 141
12 the threshold system advanced to daily thresholds based
13 on independent store dynamics, but that part you don't
14 have a date. Do you know when that occurred?

15 A. I believe that was after they opened GERx
16 because that was the advancement in technology.

17 Q. Do you intend to testify that the
18 technology employed by GERx was not available in 2013?

19 A. It wasn't available to Giant Eagle, no.

20 Q. How do you know that?

21 A. Because it was under development.

22 Q. Have you assessed whether similar
23 technological systems were already being used by other
24 distributors in 2013?

1 A. No, I have not.

2 Q. You can go to Page 50 of your report. In
3 Paragraph 144, a few sentences from the bottom, there's
4 a sentence that says furthermore, such threshold-based.

5 A. Uh-huh.

6 Q. Do you see that sentence?

7 A. Yes.

8 Q. You say furthermore, such threshold-based
9 methods are neither an effective nor a rational means
10 to detect diversion of controlled substances for
11 shipments between divisions of the same company.

12 Do you see that?

13 A. Yes.

14 Q. So do you intend to testify that the
15 thresholds are not effective method to detect
16 suspicious orders?

17 A. Yes, thre -- so threshold meth --
18 thresholds and establishing a threshold system is only
19 a tool. It cannot be used in isolation to determine
20 whether an order is suspicious or not.

21 Q. But once an order is flagged using a
22 threshold, what you should go next is doing due
23 diligence to confirm or refute whether it's actually
24 suspicious; true?

1 A. Again, the threshold is a tool and how you
2 design the tool. Every threshold system that you use
3 has fatal flaws, and you need to understand those
4 flaws, and by understanding those flaws based on the
5 nature of your business you can determine then whether
6 or not an order that is flagged needs further
7 investigation or not.

8 Q. So it's your opinion then that just
9 because an order is flagged it doesn't necessarily
10 require further due diligence?

11 A. I'm not saying it doesn't require further
12 due diligence. What I'm saying is somebody makes --
13 needs to then make a determination whether or not it
14 requires further due diligence.

15 Q. So it needs to be looked at at the very
16 least; right?

17 A. That is correct.

18 Q. What are the fatal flaws with HBC's
19 threshold system that they employed in 2013?

20 A. Oh. Well, the threshold system that they
21 had in 2013 -- it flagged orders. It was an average --
22 they used an average. They used a nation -- not
23 nationwide, but their company average, and it was
24 aggregated through the entire month.

1 So what you got is as you were reaching
2 your threshold potentially -- as you were reaching your
3 threshold you didn't hit those thresholds ever until
4 the end of the month, so it was more of a look back and
5 be able to see stores that were constantly -- or not
6 constantly, but if they were exceeding certain
7 thresholds, that somebody could keep an eye on them.

8 Q. We can go to Page 64 of your report. You
9 say in the bullet point there starting with despite
10 implementing -- do you see that?

11 A. Uh-huh.

12 Q. It says despite implementing a threshold
13 system to monitor for suspicious orders there was no
14 change in the number of suspicious orders validating
15 that existing policies and procedures were sufficient
16 to prevent theft and diversion.

17 Do you see that?

18 A. Yes.

19 Q. You agree this conclusion assumes that the
20 threshold system that was implemented was adequate;
21 right?

22 A. No, what I'm assuming what is adequate and
23 even more than adequate are Giant Eagle's policies,
24 procedures, and controls regarding theft and diversion,

1 and that the threshold system was -- it was a redundant
2 tool that they added because that seemed to be where
3 the industry going -- where the industry was going and
4 what the expectations were in the industry, and all it
5 proved is that Giant Eagle had sufficient controls to
6 prevent theft and diversion.

7 Q. But in order for the threshold system to
8 prove that, you would have to assume that it in and of
9 itself was an adequate system; right? Otherwise it
10 can't validate anything.

11 A. Right, and -- well, but based on -- but
12 even as technology advanced and their systems became
13 more sophisticated, nothing changed. They didn't
14 identify even -- they didn't identify more. So yes,
15 they may have used a rudimentary threshold system in
16 2013 that was the best thing available to them at the
17 time, but even as technology advanced and they took
18 advantage of more advanced software and more
19 complicated algorithms, the outcome was the same, which
20 is that no suspi -- or limited suspicious orders, very
21 little suspicious orders were identified, and therefore
22 you can conclude and I have concluded that their
23 controls are sufficient.

24 Q. I didn't see an analysis in your report as

225

1 So it sends the different trends, it sends
2 the prescribing habits, and it sends the ordering
3 process out of balance. When certain products are no
4 longer available, then you can see some blips or
5 disparities.

6 BY MR. BARNES:

7 Q. Is there a patient care aspect to
8 suspicious order monitoring?

9 MR. BOGLE: Object to form.

10 A. There is. The pharmacy organization --
11 the pharmacy itself. Let's start there.

12 Pharmacists are trained to take care of
13 their patients, and you can't take care of your
14 patients if you don't have product on the shelf. So
15 you have an obligation as a pharmacist to carry the
16 products that your patient base needs, and when you
17 can't get those products from your wholesaler, it's
18 devastating, and you can no longer take care of your
19 patient, and therefore you have to tell your patient to
20 go somewhere else.

21 So it's important that whatever suspicious
22 order monitoring threshold, program, and all of the
23 different tools that you use -- the things that you put
24 together need to follow the law, and you need to be

226

1 compliant, but you also have to remember patient care
2 so that you don't unnecessarily slow things down or
3 disrupt access that can cause further ramifications
4 down the line, which includes further harm to the
5 patient.

6 BY MR. BARNES:

7 Q. So if I'm interesting you correctly, that
8 part of this analysis about suspicious orders is -- is
9 your testimony that you have to take into account the
10 legitimate needs of patients?

11 MR. BOGLE: Object to form.

12 A. Yes. You can't just stop an order because
13 it's flagged by a system, because by stopping that
14 order that drug is not getting to the store and
15 therefore the store then can't fill prescriptions.

16 BY MR. BARNES:

17 Q. You know Dr. McCann -- he had like five
18 different ways of playing with the numbers in terms of
19 how many suspicious orders, and do you recall one of
20 his methodologies would have identified upwards of 80
21 to 90 percent of every order ever input by everybody as
22 suspicious? Does that make any sense to you
23 whatsoever?

24 MR. BOGLE: Object to form.

1 A. No, it makes absolutely no sense. His
2 methodologies were full of flaws.

3 BY MR. BARNES:

4 Q. Are you aware of the DEA being required to
5 consider patient needs and making sure there was an
6 adequate supply getting to the patients as part of
7 their regulatory obligations?

8 MR. BOGLE: Object to form.

9 A. The DEA's regular -- and where I would
10 apply this is in their quotas, as the DEA is
11 determining how quotas are formed and what they should
12 be used for. The DEA's obligation is to make sure that
13 there is enough product in market to meet the needs and
14 the demand of the patients.

15 BY MR. BARNES:

16 Q. You provided a lot of testimony and your
17 report specifically addresses HBC and the GERx
18 warehouse at Giant Eagle?

19 A. Yes.

20 Q. And you've -- I don't want to go over
21 everything, but you've opined that Giant Eagle has met
22 the Controlled Substances Act in many different ways
23 and in some ways exceeded the requirements of that act?

24 A. Yes.

1 Q. And does that cover the time period in
2 which HBC and GERx were actually distributing
3 controlled substances?

4 A. Yes.

5 Q. And that began when; do you know?

6 A. In 2009.

7 Q. When you talked about the suspicious order
8 monitoring, were you limiting your testimony in any way
9 to so-called threshold systems that use formulas or
10 algorithms?

11 MR. BOGLE: Object to form.

12 A. No, as I've stated before, threshold
13 systems are only a tool to be used as potentially --
14 you don't even have to use it. It's not even required
15 by law, but you can use a threshold-type system as a
16 tool in your toolbox as it relates to a suspicious
17 order monitoring program.

18 BY MR. BARNES:

19 Q. You were asked some questions about being
20 licensed and what that means. I just want to follow up
21 with a few questions. Were you testifying that simply
22 having a license meant you were in compliance, or
23 something else?

24 MR. BOGLE: Object to form.

1 A. By having a license, the regulatory
2 authority has said that you have controls, policies,
3 and procedures in place they find legally relevant to
4 rules and regulations that they have created and
5 they're enforcing.

6 BY MR. BARNES:

7 Q. And you talked a little bit about
8 preinspection -- preinspections by the DEA. And by
9 pre, I mean before you start distributing, another
10 inspection right after you start distributing, and then
11 periodic inspections throughout the time you are
12 distributing -- is that -- am I summarizing your
13 testimony correctly?

14 MR. BOGLE: Object to form.

15 A. Yes.

16 BY MR. BARNES:

17 Q. Now are those inspections rigorous or are
18 they flimsy or somewhere in between?

19 MR. BOGLE: Object to form.

20 A. No, those inspections are extremely
21 rigorous, and they give full feedback whether or not
22 you're meeting their expectations of what needs to
23 occur.

24 BY MR. BARNES:

230

1 Q. Does it include a review of suspicious
2 order monitoring systems?

3 A. It does.

4 MR. BOGLE: Object to form.

5 BY MR. BARNES:

6 Q. Does it include a review of inventory
7 management systems?

8 A. It does.

9 Q. Does it include a detailed review of
10 transactions within your systems to make sure controls
11 are in place and working?

12 MR. BOGLE: Object to form.

13 A. Yes.

14 BY MR. BARNES:

15 Q. And did you see testimony in the record
16 for the Giant Eagle depositions that HBC and GERx were
17 subjected to pre-inspections, post-inspections, and
18 audits -- periodic audits?

19 A. Yes, I did see that testimony.

20 Q. And did you also see the testimony that
21 the DEA never once suggested that Giant Eagle was not
22 in compliance?

23 MR. BOGLE: Object to form.

24 A. The DEA did not find any deficiencies.

1 BY MR. BARNES:

2 Q. And is that an important factor for you
3 when you made the evaluations you did in this case and
4 came to the conclusions that you did?

5 A. Absolutely, yes.

6 Q. You were asked some questions about
7 training -- training at Giant Eagle. Do you recall any
8 deposition testimony about so-called CBT,
9 computer-based training?

10 A. I do, yes.

11 Q. And do you recall specifically the Walt
12 Durr and Greg Carlson depositions talking about
13 training?

14 MR. BOGLE: Object to form.

15 A. Yes, they went -- they spoke of the
16 different training modalities from computer-based
17 training to even having trainers. Their PDLs often
18 gave little mini training seminars or on-the-job
19 training, so it was constant education on the policies,
20 procedures, and controls that Giant Eagle wanted them
21 to follow.

22 BY MR. BARNES:

23 Q. Is that pretty standard in the industry in
24 your experience -- that type of training?